

Docket No. 241331US20



JFCO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Patricia B HOYER, et al.

SERIAL NO: 10/650,799

FILED: August 29, 2003

FOR: ANIMAL MODEL FOR PERIMENOPAUSE AND MENOPAUSE AND METHODS OF INDUCING OVARIAN FAILURE

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s) is attached along with PTO 1449.
- A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

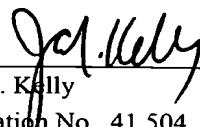
- Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Eckhard H. Kuesters



A handwritten signature in black ink, appearing to read "J. J. Kelly".

James J. Kelly

Registration No. 41,504

Customer Number

22850

Tel. (703) 413-3000
Fax. (703) 413-2220
(OSMMN 05/03)



Form PTO 1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. 241331US20	SERIAL NO. 10/650,799
LIST OF REFERENCES CITED BY APPLICANT		APPLICANT Patricia B. HOYER, et al.	
		FILING DATE August 29, 2003	GROUP 1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
AA	6,107,540	08/22/00	Sawyer et al			
AB	6,583,334	06/24/03	Haslam			
AC						
AD						
AE						
AF						
AG						
AH						
AI						
AJ						
AK						
AL						
AM						
AN						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES	NO
	AO					
	AP					
	AQ					
	AR					
	AS					
	AT					
	AU					
	AV					

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

AW	Miriam J.J. de Kleijn et al.; "Endogenous Estrogen Exposure and Cardivascular Mortality Risk in Postmenopausal Women"; American Journal of Epidemiology, Vol. 155, No. 4, pp. 339-345; 2002	
AX	Caren G. Solomon et al.; "Menstrual Cycle Irregularity and Risk for Future Cardivascular Disease"; The Journal of Clinical Endocrinology & Metabolism, 87(5), pp. 2013-2017; 2002	
AY	Frank B. Hu, MD et al.; "Age at Natural Menopause and Risk of Cardivascular Disease"; Arch Intern Med/Vol 159, pp. 1061-1066; May 24, 1999	
AZ	Francine Grodstein et al; "A Prospective, Observational Study of Postmenopausal Hormone Therapy and Primary Prevention of Cardiovascular Disease"; Annals of Internal Medicine, Vol. 133, No. 12; pp. 933-941; December 19, 2000	<input checked="" type="checkbox"/> Additional References sheet(s) attached

Examiner _____ Date Considered _____

*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO 1449 (Modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT		ATTY DOCKET NO. 241331US20	SERIAL NO. 10/650,799
		APPLICANT Patricia B HOYER, et al.	
		FILING DATE August 29, 2003	GROUP 1632
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)			
AAA	Francine Grodstein et al; "Postmenopausal Hormone Use and Secondary Prevention of Coronary Events in the Nurses' Health Study"; Annals of Internal Medicine; Vol. 135, No. 1, pp. 1-8; July 3, 2001		
AAB	Frank B. Hu, MD et al.; "Postmenopausal Hormone Therapy and the Risk of Cardiovascular Disease: The Epidemiologic Evidence"; The American Journal of Cardiology; Vol. 90(1A), pp. 26F-29F; July 3, 2002		
AAC	NIH: Postmenopausal Hormone Therapy Information; http://www.nih.gov/PHTindex.htm ; 4pp.		
AAD	Karin H. Humphries et al; "Risks and benefits of hormone replacement therapy: The evidence speaks"; Canadian Medical Association, 168(8), pp. 1001-1010; April 15, 2003		
AAE	Gail A. Laughlin et al; "Hysterectomy, Oophorectomy, and Endogenous Sex Hormone Levels in Older Women: The Rancho Bernardo Study"; The Journal of Clinical Endocrinology & Metabolism"; Vol. 85, No. 2, pp. 645-651; 2000		
AAF	Manuel Neves-e-Castro et al; "Results from WHI and HERS II - Implications for Women and the prescriber of HRT"; Maturitas 42 (2002) 255-258		
AAG	Bjarne K. Jacobsen et al' "Age at Natural Menopause and All-Cause Mortality: A 37-Year Follow-up of 19/731 Norwegian Women"; American Journal of Epidemiology, Vol. 157, No. 10, pp. 923-929; 2003		
AAH	Sally A. Shumaker, Ph.D. et al; "Estrogen Plus Progestin and the Incidence of Dementia and Mild Cognitive Impairment in Postmenopausal Women The Women's Health Initiative Memory Study: A Randomized Controlled Trial"; JAMA, Vol. 289, No. 20 (Reprinted), pp. 2651-2662; May 28, 2003		
AAI	Peter P. Zandi, Ph.D. et al.; "Hormone Replacement Therapy and Incidence of Alzheimer Disease in Older Women The Cache County Study"; JAMA, Vol. 288, No. 17, pp. 2123-2129; November 6, 2002		
AAJ	Susan M. Fontaine et al; "Stereochemical Aspects of Vinylcyclohexene Bioactivation in Rodent Hepatic Microsomes and Purified Human Cytochrome P450 Enzyme Systems"; DMD, Vol. 29, No. 2, pp. 179-184; 2001		
AAK	S.M. Borman et al; "Ovotoxicity in Female Fischer Rats and B6 Mice Induced by Low-Dose Exposure to Three Polycyclic Aromatic Hydrocarbons: Comparison through Calculation of an Ovotoxic Index"; Toxicology and Applied Pharmacology, Vol. 167, pp. 191-198; 2000		
AAL	Patricia B Hoyer et al; "Ovarian Toxicity of 4-Vinylcyclohexene Diepoxide: A Mechanistic Model"; Toxicologic Pathology, Vol. 29, No. 1, pp. 91-99; 2001		
AAM	Patricia B. Hoyer et al; "Assessment of Follicle Destruction in Chemical-Induced Ovarian Toxicity"; Annu. Rev. Pharmacol. Toxicol., Vol. 36, pp. 307-331; 1996		
AAN	Loretta P. Mayer et al; "Long-term effects of ovarian follicular depletion in rats by 4-vinylcyclohexene diepoxide"; Reproductive Toxicology, Vol. 16, pp. 775-781; 2002		
AAO	Stephen B. Hooser et al; "Long-Term Ovarian and Gonadotropin Changes in Mice Exposed to 4-Vinylcyclohexene"; Reproductive Toxicology, Vol. 8, No. 4, pp. 315-323; 1994		
AAP	Bill J. Smith et al; "The Role of Epoxidation in 4-Vinylcyclohexene-Induced Ovarian Toxicity"; Toxicology and Applied Pharmacology, Vol. 105, pp. 372-381; 1990		
AAQ	L.N. Springer et al; "Involvement of Apoptosis in 4-Vinylcyclohexene Diepoxide-Induced Ovotoxicity in Rats" Toxicology and Applied Pharmacology, Vol. 139, pp. 394-401; 1996		
Examiner		Date Considered	
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. 241331US20	SERIAL NO. 10/650,799
LIST OF REFERENCES CITED BY APPLICANT		APPLICANT Patricia B HOYER, et al.		
		FILING DATE August 29, 2003	GROUP 1632	

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

AAA	P.J. Devine et al; "Ultrastructural Evaluation of Oocytes During Atresia in Rat Ovarian Follicles"; Biology of Reproduction, Vol. 63, pp. 1245-1252; 2000
AAB	Xiaming Hu et al; "Expression and Redistribution of Cellular Bad, Bax and Bcl-X _L Protein Is Associated with VCD-Induced Ovotoxicity in Rats"; Biology of Reproduction, Vol. 65, pp. 1489-1495; 2001
AAC	Xiaoming Hu et al; "Apoptosis Induced in Rats by 4-Vinylcyclohexene Diepoxide is Associated with Activation of Caspase Cascades"; Biology of Reproduction, Vol. 65, pp. 87-93; 2001
AAD	Xiaoming Hu et al; "Activation of Mitogen-Activated Protein Kinases and AP-1 Transcription Factor in Ovotoxicity Induced by 4-Vinylcyclohexene Diepoxide in Rats"; Biology of Reproduction, Vol. 67, pp. 718-724; 2002
AAE	S.M. Borman et al; "Single Dose of the Ovotoxicant 4-Vinylcyclohexene Diepoxide Is Protective in Rat Primary Ovarian Follicles"; Toxicology and Applied Pharmacology, Vol. 158, pp. 244-252; 1999
AAF	Kary E. Tohmpson et al; "17 β -Estradiol Affords Protection against 4-Vinylcyclohexene Diepoxide-Induced Ovarian Follicle Loss in Fischer-344 Rats"; Endocrinology, 143(3), pp. 1058-1065; March 2002
AAG	Lori Mosca, MD et al; "Cardiovascular Disease in Women A Statement for Healthcare Professionals From the American Heart Association"; Circulation, Vol. 96, No. 7, pp. 2468-2482; October 7, 1997
AAH	Suzanne Oparil; Supplement to Hypertension; Arthur C. Corcoran Memorial Lecture; "Hormones and Vasoprotection"; Journal of the American Heart Association, Vol. 33, No. 1, Part II; January 1999
AAI	Stephen Hulley, MD et al; "Randomized Trial of Estrogen Plus Progestin for Secondary Prevention of Coronary Heart Disease in Postmenopausal Women"; JAMA, Vol. 280, No. 7, pp. 605-613; August 19, 1998
AAJ	Dr. Anderson et al; "Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women"; JAMA, Vol. 288, No. 3, pp. 321-333; July 17, 2002
AAK	David W. Purdie; "Consequences of long-term hormone replacement therapy"; British Medical Bulletin, Vol. 56, No. 3, pp. 809-823; 2000
AAL	Carmen Rodriguez, MD, MPH et al; "Estrogen Replacement Therapy and Ovarian Cancer Mortality in a Large Prospective Study of US Women"; JAMA, Vol. 285, No. 11, pp. 1460-1465; March 21, 2001
AAM	Francis L. Bellino, Ph.D.; "Nonprimate Animal Models of Menopause: Workshop Report"; Menopause: The Journal of the North American Menopause Society, Vol. 7, No. 1, pp. 14-24; 2000
AAN	Howard L. Judd, MD; "Hormonal Dynamics Associated with the Menopause"; Clinical Obstetrics and Gynecology, Vol. 19, No. 4, pp. 775-788; December 1976
AAO	Jodi A. Flaws et al; "Destruction of Preantral Follicles in Adult Rats By 4-Vinylcyclohexene Diepoxide"; Reproductive Toxicology, Vol. 8, No. 6, pp. 500-514; 1994
AAP	Shao-Wen Kao et al; "Early Effects of Ovotoxicity Induced By 4-Vinylcyclohexene Diepoxide in Rats and Mice"; Reproductive Toxicology, Vol. 13, No. 1, pp. 67-75; 1999
AAQ	Gregory F. Erickson; Menopause Biology and Pathobiology; "Ovarian Anatomy and Physiology"; Chapter 2, pp. 13-31; 2000

Examiner

Date Considered

*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO 1449 (Modified) LIST OF REFERENCES CITED BY APPLICANT		ATTY DOCKET NO. 241331US20	SERIAL NO. 10/650,799
		APPLICANT Patricia B HOYER, et al.	
		FILING DATE August 29, 2003	GROUP 1632
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)			
AAA	Cheryl A. Dyer, Ph.D., Alzheimer's Association, KRS: Application form for Individual Research Project, Project Title: Apo E isoform effect on perimenopausal ovarian steroids and risk for AD		
AAB	Patricia B. Hoyer, Research Plan, Grant Application, PHS 398/2590, pp. 17-47.		
AAC	Loretta P. Mayer, Grant Proposal, AIM III, p. 25.		
AAD	Loretta P. Mayer et al., Preprint of an article entitled "The Follicle-Depleted Mouse Ovary Produces Androgen		
AAE	Loretta P. Mayer et al., July 2001 Presentation to the Ottawa Society for Study of Reproduction, "Long-Term Effects of Ovotoxicity in Rats Exposed to 4-Vinylcyclohexene Diepoxide.		
AAF	Loretta P. Mayer et al., Abstract and Poster Presentation, "An ovary-intact mouse model that mimics peri-menopause in women", Published after September 20, 2002.		
AAG	L.P. Mayer et al., Abstract and Poster Presentation at the Endocrinology annual meeting in San Francisco, "Development of an Ovary-Intact Murine Model for the Study of Menopause-related Pathologies", June 2002.		
AAH	GM Buss et al., Abstract and Poster Presentation, Presented at the Mountain West Society for Toxicology, September 20, 2001, "Steroidogenic Responsiveness of 4-Vinylcyclohexene Diepoxide (VCD-Induced Follicle-Deplete Murine Ovaries to Gonadotropin Stimulation In Vitro".		
AAI	Hoyer and Mayer, "Background and Significance," Unpublished Summary, March 2002, pp. 1-7.		
AAJ	Loretta P. Mayer et al., Poster Presentation at the Atherosclerosis, Thrombosis and Vascular Biology Meeting of the American Heart Association, Spring (March?) 2002.		
AAK	In House Talk done By 10/30/01, entitled "Mouseopause: A model whose time has come.		
AAL			
AAM			
AAN			
AAO			
AAP			
AAQ			
Examiner		Date Considered	
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			